# COCIR Position Paper

## Negative Impact of EMF Directive on the Healthcare Industry

(Protection of Workers against Exposure to Electromagnetic Fields)

**The Background to the EMF Directive**
In April 2004, the European Council adopted the European Directive (2004/40/EC) regarding the exposure of workers to the risks arising from EMF. EU Members States must transpose the Directive into national legislation by 2008.

**Magnetic resonance imaging** is an essential diagnostic tool in healthcare today. The early developers of this important medical technology were awarded the 2003 Nobel Price for Medicine.

**The Directive in Practice**
The EMF Directive contains limit values that will limit the use of Magnetic Resonance (MR) equipment and may prevent certain applications. These exposure limits, for frequencies between 0 and 300 GHz, will apply to workers using MR equipment. This will affect the use of MR for medical diagnosis and treatment as well as the service, maintenance, development and manufacturing of equipment.

Users and manufacturers of MR equipment could be affected by the EMF Directive in numerous ways as described in the Annex. In the 30 years' history of the use of MR for medical purposes with more than 500 million patients, no significant events have been reported that relate to EMF exposure.

As a result of implementation there would be **restricted availability of MR** diagnostic tools. Secondly, it would result in an increase in the use of X-ray based imaging modalities. In addition, the Directive may severely limit any future developments to enhance the capabilities of MR equipment. One example is the use of MR during minimally invasive procedures.

**The COCIR Position on EMF**
COCIR members are committed to maintaining high levels of safety for both patients and users. COCIR members are actively involved in developing international safety standards.

COCIR supports claims in recent publications (see annex) that the limit values set in the current Directive are not substantiated by sound scientific and clinical data.

COCIR is calling for these **limit values to be urgently reviewed** for the healthcare sector on the basis of specifically conducted clinical research. Until this is done, people working with MR equipment must be **exempted from the scope** of this Directive because of the enormous burden it will put on healthcare users (MR staff, MR factory workers, service personnel and volunteers) and patients. Such an exemption would not compromise the safety of workers as safety in the MR sector is addressed by specific international standards. (See annex)

ANNEX

**Examples of impact on workers and manufacturers caused by the requirements of the current EMF Directive**

- The operator positioning the patient on the MR system will typically not be exposed to EMF other than the static magnetic field. However, in some situations the exposure levels of medical staff are higher than permitted in the EMF Directive e.g. when the user is near the system during scanning to calm the patient or to check on their condition.
- With interventional procedures the physician or other medical professionals must be near the equipment during scanning to perform the intervention. This kind of interventional procedures is likely to become more common in the near future.
- During maintenance and repair the service engineer may be exposed to EMF fields higher than the limits set out in the EMF Directive.
- During the development and manufacturing cycle of MR equipment, system engineers may be exposed to EMF fields higher than the limits set out in the EMF Directive.

**References:**


- Impact of Electromagnetic Field Exposure limits in Europe: Is the future of Interventional MRI Safe?, DLG Hill, K Mcleish, SF Keevil, Academic Radiology, Vol.12, No 9, p1135-1142, September 2005.
- An analysis of differences in the low-frequency electric and magnetic field exposure standards of ICES and ICNIRP, JP Reilly, Health Physics, Vol. 89, Number 1, p71-80, July 2005.